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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT

PAPER NUMBER

3761

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/812,755

Applicant(s)
Loeffler et al.

Examiner
Joseph Weiss

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3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 5 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 & 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Singier (US 3325031).

In regards to claim 1, Singier discloses a fluid filled ampoule (Figs 1-3 & 8) having an ampoule body (Figs 1-3 & 8) with a top (12) and bottom (11) end and a sealed interior (space defined by structure), a top tab (35) coupled to the top end which is removable to create a drain vent in the top end, a bottom tab (20/23 complex) coupled to the bottom end and removable to create a drain opening in the bottom end (see fig 4 & supporting text) and a movable shroud (32) which is disposed about the top tab.

In regards to claim 3, Singier discloses the shroud as being bendable to provide easy access to the top tab (Note fig 5).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singier.

In regards to claim 2, Singier discloses the top & bottom tabs as being coupled to the body of the ampoule (note fig 2) in such a way that they are fully capable of being removed via a twist action.

In regards to claim 6, Singier discloses the bottom end being tapered (11) which provides a surface area at the bottom end which is fully capable of providing a seal when engaging a corresponding receiver of a dispensing device.

In regards to claim 7, Singier as noted above substantially disclose the claimed invention except for the precise wall thickness of "about" 0.03 inches.

It is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather

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than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singier as applied to claim 1 above, and further in view of Mauro, Jr et al. (US 4101041).

In regards to claim 4, Singier substantially discloses the instant application's claimed invention, to include a rail structure (corners between sections 13) but does not explicitly disclose the use of a pair of longitudinal rails on the ampoule body that are adapted to guide the ampoule into a receiver of an aerosolization device. However, Mauro disclose such (note rails/track/orifice structure 20, 26 & 28). The references are analogous since they are from the same field of endeavor, the dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Mauro and used them with the device of Singier. The suggestion/motivation for doing so would have been to permit a more secure fitting-interface between the reservoir and the device it is being used with. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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In regards to claim 5, the reference noted above substantially disclose the claimed invention in include a means to insure only one orientation of insertion of the ampoule relative to a device will occur (note openings 28 at only one end of track/rails 20/26 with the opposing end being sealed off preventing a reverse insertion) except for the sizing of the rails to establish orientation of entry, an interchangeable mechanical equivalent to perform/achieve the same function/intended result.

It is noted that applicant's specification does not set forth this equivalent alternative arrangement, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

6. Claims 11-17 & 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singier in view of Mauro, Jr.

In regards to claim 11, Singier discloses a fluid filled ampoule (Figs 1-3 & 8) having an ampoule body (Figs 1-3 & 8) with a top (12) and bottom (11) end and a sealed interior (space defined by structure), both ends being adapted to be opened to provide respective vent and drain openings (see fig 4 & supporting text), but does not explicitly disclose at least one orientation element to facilitate proper insertion of the ampoule into an aerosolization device. However, Mauro disclose such (note openings 28 at only one end of track/rails 20/26 with the opposing end

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being sealed off preventing a reverse insertion). The references are analogous since they are from the same field of endeavor, the medicament dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Mauro and used them with the device of Singier. The suggestion/motivation for doing so would have been to insure the proper and correct fitting-interface between the reservoir and the device it is being used with to facilitate proper overall function. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 12, the suggested device discloses such as orientation device as being longitudinal rails. (Element 20 of Mauro)

In regards to claim 13, Mauro substantially disclose the claimed invention in include a means to insure only one orientation of insertion of the ampoule relative to a device will occur (note openings 28 at only one end of track/rails 20/26 with the opposing end being sealed off preventing a reverse insertion) except for the sizing of the rails to establish orientation of entry, an interchangeable mechanical equivalent to perform/achieve the same function/intended result.

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It is noted that applicant's specification does not set forth this equivalent alternative arrangement, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 14, the suggested device discloses a top tab (35 of Singier) coupled to the top end which is removable to create a drain vent in the top end, a bottom tab (20/23 complex of Singier) coupled to the bottom end and removable to create a drain opening in the bottom end (see fig 4 & supporting text of Singier).

In regards to claim 15, the suggested device discloses the top & bottom tabs as being coupled to the body of the ampoule (note fig 2 of Singier) in such a way that they are fully capable of being removed via a twist action.

In regards to claim 16, the suggested device discloses and a movable shroud (32) which is disposed about the top tab and as being bendable to provide easy access to the top tab (Note fig 5 of Singier).

In regards to claim 17, the suggested device discloses the bottom end being tapered (11 of Singier) which provides a surface area at the bottom end which is fully capable of providing a seal when engaging a corresponding receiver of a dispensing device.

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In regards to method claims 31-37, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 11-17.

7. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singier as applied to claim 1 above, and further in view of Haver (WO92/17231).

In regards to claim 8, Singier substantially discloses the instant application's claimed invention, but does not explicitly disclose at least one keying element on the ampoule body that is adapted to permit operation of an aerosolization device when the keying element is accepted by the aerosolization device. However, Haver disclose such (note bands 58 & chip 62). The references are analogous since they are from the same field of endeavor, the medicament dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Haver and used them with the device of Singier. The suggestion/motivation for doing so would have been to insure operation of the dispenser only when the proper ampoule under the proper conditions is placed within the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather

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than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 9, the reference noted above substantially disclose the claimed invention to include the use of protrusions to serve as a keying element (56 & 57) but they are arranged on the aerosol device instead of the ampoule reservoir body, i.e. a mere reversal or rearrangement of known parts for a known purpose.

It is noted that applicant's specification does not set forth this mere reversal/rearrangement of known parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 10, the suggested device discloses the keying element comprising a readable pattern on the ampoule body (see bands 58 & chip 62).

8. Claims 18-20 & 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singier & Mauro as applied to claim 11 above, and further in view of Haver (WO92/17231).

In regards to claim 18, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose at least one keying element on the ampoule body that is adapted to permit operation of an aerosolization device when the keying element is accepted by the aerosolization device. However, Haver disclose such (note bands 58

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& chip 62). The references are analogous since they are from the same field of endeavor, the medicament dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Haver and used them with the suggested device. The suggestion/motivation for doing so would have been to insure operation of the dispenser only when the proper ampoule under the proper conditions is placed within the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 19, the reference noted above substantially disclose the claimed invention to include the use of protrusions to serve as a keying element (56 & 57) but they are arranged on the aerosol device instead of the ampoule reservoir body, i.e. a mere reversal or rearrangement of known parts for a known purpose.

It is noted that applicant's specification does not set forth this mere reversal/rearrangement of known parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

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Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 20, the suggested device discloses the keying element comprising a readable pattern on the ampoule body (see bands 58 & chip 62).

In regards to method claims 38-39, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 18-20.

9. Claims 21-24, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singier in view of Haver (WO92/17231).

In regards to claim 21, Singier discloses a fluid filled ampoule (Figs 1-3 & 8) having an ampoule body (Figs 1-3 & 8) with a top (12) and bottom (11) end and a sealed interior (space defined by structure), both ends being adapted to be opened to provide respective vent and drain openings (see fig 4 & supporting text), but does not explicitly disclose at least one keying element on the ampoule body that is adapted to permit operation of an aerosolization device when the keying element is accepted by the aerosolization device. However, Haver disclose such (note bands 58 & chip 62). The references are analogous since they are from the same field of endeavor, the medicament dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of

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Haver and used them with the device of Singier. The suggestion/motivation for doing so would have been to insure operation of the dispenser only when the proper ampoule under the proper conditions is placed within the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 22, the reference noted above substantially disclose the claimed invention to include the use of protrusions to serve as a keying element (56 & 57) but they are arranged on the aerosol device instead of the ampoule reservoir body, i.e. a mere reversal or rearrangement of known parts for a known purpose.

It is noted that applicant's specification does not set forth this mere reversal/rearrangement of known parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 23, the suggested device discloses the keying element comprising a readable pattern on the ampoule body (see bands 58 & chip 62).

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In regards to claim 24, the suggested device discloses the use of at least one orientation element to facilitate proper insertion of the ampoule into the aerosolization device (See element 22 of Haver).

In regards to claim 27, the suggested device discloses the bottom end being tapered (11 of Singier) which provides a surface area at the bottom end which is fully capable of providing a seal when engaging a corresponding receiver of a dispensing device.

In regards to claim 28, the suggested device discloses a top tab (35 of Singier) coupled to the top end which is removable to create a drain vent in the top end, a bottom tab (20/23 complex of Singier) coupled to the bottom end and removable to create a drain opening in the bottom end (see fig 4 & supporting text of Singier).

In regards to claim 29, the suggested device discloses the top & bottom tabs as being coupled to the body of the ampoule (note fig 2 of Singier 20/23 & 35) in such a way that they are fully capable of being removed via a twist action.

In regards to claim 30, the suggested device discloses and a movable shroud (32) which is disposed about the top tab and as being bendable to provide easy access to the top tab (Note fig 5 of Singier).

10. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singier & Haver as applied to claim 24 above, and further in view of Mauro.

In regards to claim 25, the suggested device substantially discloses the instant application's claimed invention, to include a rail structure (corners between sections 13 of Singier)

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but does not explicitly disclose the use of a pair of longitudinal rails on the ampoule body that are adapted to guide the ampoule into a receiver of an aerosolization device. However, Mauro disclose such (note rails/track/orifice structure 20, 26 & 28). The references are analogous since they are from the same field of endeavor, the dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Mauro and used them with the suggested device. The suggestion/motivation for doing so would have been to permit a more secure fitting-interface between the reservoir and the device it is being used with. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 26, the reference noted above substantially disclose the claimed invention in include a means to insure only one orientation of insertion of the ampoule relative to a device will occur (note openings 28 at only one end of track/rails 20/26 with the opposing end being sealed off preventing a reverse insertion) except for the sizing of the rails to establish orientation of entry, an interchangeable mechanical equivalent to perform/achieve the same function/intended result.

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It is noted that applicant's specification does not set forth this equivalent alternative arrangement, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Double Patenting

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 1-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-30 of copending Application Nos. 09/876542, 09/876402. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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13. Claims 1-30 of this application conflict with claims 1-30 of Application Nos 09/876542, 09876402 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Conclusion


14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US5122116, 4934358, 4693853, 4248227, 4207990, 4052986, 3993223, 3951313, 3908654, 2764979, 2022520, 1680616, 550315,

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. F. Weiss

January 2, 2003



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